UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

In re: OXYCONTIN ANTITRUST LITIGATION	04-md-1603 (SHS) This document relates to:
PURDUE PHARMA L.P., THE P.F. LABORATORIES, INC., and PURDUE PHARMACEUTICALS L.P., Plaintiffs, v. APOTEX INC. and APOTEX CORP., Defendants.	Civil Action No. 07 CIV 8002 (SHS) THIS DOCUMENT WAS FILED ELECTRONICALLY VIA CM/ECF

PURDUE'S REPLY TO THE COUNTERCLAIMS SET FORTH IN DEFENDANTS APOTEX, INC.'S AND APOTEX CORP.'S ANSWERS, DEFENSES AND COUNTERCLAIMS

Plaintiffs Purdue Pharma L.P., The P.F. Laboratories Inc., and Purdue Pharmaceuticals L.P. (collectively, "Purdue") reply to Defendants Apotex Inc. and Apotex Corp.'s ("Apotex") Counterclaims as follows:

REPLY

1. Apotex purports to state causes of action based on alleged misconduct during the prosecution of Purdue patents before the United States Patent and Trademark Office ("PTO") and based on allegations that Purdue has wrongly brought suit to enforce its patents. Except as expressly admitted, Purdue denies the averments of Paragraph 1.

2. Denied.

3. Admitted on information and belief.

4. Admitted on information and belief.

5. Denied as to "Purdue Pharma., L.P."; admitted as to "Purdue Pharma L.P."

6. Denied as to "P.F. Laboratories Inc."; admitted as to "The P.F. Laboratories, Inc."

7. Admitted.

8. Apotex purports to base jurisdiction on the statutes listed in Paragraph 8. Except as expressly admitted, Purdue denies the averments of Paragraph 8.

9. Apotex purports to base subject matter jurisdiction on the statutes listed in Paragraph 9. Purdue does not contest that subject matter jurisdiction exists. Except as expressly admitted, Purdue denies the averments of Paragraph 9.

10. Venue and personal jurisdiction in this Judicial District are proper. Except as expressly admitted, Purdue denies the averments of Paragraph 10.

11. Purdue sells controlled-release oxycodone hydrochloride under the trademark OxyContin® and owns patents which are, or have been, listed by the FDA in the FDA's "Orange Book" (*Approved Drug Products With Therapeutic Equivalence Evaluation*) and which contain one or more claims covering OxyContin® or its method of use. Except as expressly admitted, Purdue denies the averments of Paragraph 11.

12. Admitted.

13. Admitted.

14. Admitted on information and belief.

15. In a letter dated August 1, 2007 addressed to Purdue Pharma L.P. and "Euro-Celtigue, S.A.", Apotex sent "notice" with respect to its Oxycodone Hydrochloride CR Tablets 10, 20, 40, and 80 mg, and the '042 patent. The plaintiffs received Apotex's letter on or about August 2, 2007. Except as expressly admitted, Purdue denies the averments of Paragraph 15.

16. Admitted.

REPLY TO COUNTERCLAIM COUNT I

17. Paragraph 17 of Apotex's Counterclaims "adopt[s] by reference, repeat[s] and reallege[s]" Paragraphs 20-130 of its affirmative defenses. Purdue's responses to each of those paragraphs are numbered below as subparagraphs 17.20 to 17.130.

17.20. Denied.

17.21. Denied.

17.22. Denied.

17.23. Denied.

17.24. Denied.

17.25. Paragraph 17.25 correctly identifies the application number for the specified patents except for the '331 patent. The application number of the '331 patent is 07/800,549, not 07/800,509. Paragraph 17.25 also correctly identifies the filing date and issue date for the specified patents except for the '912 patent. The '912 patent originated as PCT application no. PCT/US92/10146 filed November 25, 1992, entered the U.S. national phase as U.S. patent application no. 81,302 on June 18, 1993, and issued on August 27, 1996. Paragraph 17.25 also correctly identifies the named inventors for the '598, '075, and '331 patents. Paragraph 17.25 also states correct file history information for each patent except for the '295 patent. The '295 patent is a continuation of the '912 patent, not a continuation-in-part. (*See* '295 patent, col. 1, lines 4-7). Except as expressly admitted, Purdue denies the averments of Paragraph 17.25.

17.26. Admitted.

17.27. Admitted.

17.28. Euroceltique is a company in whose name Purdue prosecutes and maintains patents. Except as expressly admitted, Purdue denies the averments of Paragraph 17.28.

17.29. Euroceltique is a company in whose name Purdue prosecutes and maintains patents. Except as expressly admitted, Purdue denies the averments of Paragraph 17.29.

17.30. Admitted.

17.31. The '598 and '075 patents are prior art to '912, '042, and '295 under one or more subsections of 35 U.S.C. § 102. Except as expressly admitted, Purdue denies the averments of Paragraph 17.31.

17.32. During prosecution of the '912 patent application, at the Examiner's suggestion, Purdue amended the specification "to obtain the benefit of the filing date of the prior application." ('912 file history, Paper #10, Sept. 12, 1995, p. 1). Purdue did not assert that any of the pending claims was entitled to the priority date of the '331 application. At no time did the Examiner or Purdue rely on the '331 filing date in response to a prior art rejection. In addition, all of the pertinent facts regarding the '331 patent were before the Examiner: the application, its disclosure, its inventors, and its dates. And the Examiner was aware that the '912 application "adds and claims additional disclosure not presented in the prior application." ('912 file history, Paper #9, June 12, 1995, p. 2). Except as expressly admitted, Purdue denies the averments of Paragraph 17.32.

17.33. None of the claims of the '912 patent as issued are completely supported by the original disclosure of the '331 patent. Except as expressly admitted, Purdue denies the averments of Paragraph 17.33.

17.34. The claims of the '912 patent as issued are not entitled to the benefit of the filing date of the '331 patent. Except as expressly admitted, Purdue denies the averments of Paragraph 17.34.

17.35. The response filed October 22, 1992 during the '331 prosecution stated that "the presently claimed controlled release oxycodone formulations acceptably control pain over a substantially narrower, approximately four-fold (10 to 40 mg every 12 hours – around the clock dosing) in approximately 90% of patients" and that "[t]his is in sharp contrast to the approximately eight-fold range required for approximately 90% of patients for opioid analgesics in general." Except as expressly admitted, Purdue denies the averments of Paragraph 17.35.

17.36. Language similar to that quoted in Purdue's reply to Paragraph 17.35 appears on one other occasion in the '331 file history (*see* Paper #8, March 12, 1993), one occasion in the '912 file history (*see* Paper #8, February 22, 1995) and in the specification of the '912, '042, and '295 patents. Except as expressly admitted, Purdue denies the averments of Paragraph 17.36.

17.37. Language similar to that quoted in Purdue's reply to Paragraph 17.35 appears in two papers submitted during the '331 prosecution and in one paper submitted during the '912 prosecution. Except as expressly admitted, Purdue denies the averments of Paragraph 17.37.

17.38. The word "surprising" is a common term in patent prosecution. Except as expressly admitted, Purdue denies the averments of Paragraph 17.38.

17.39. The allegations set forth in Paragraph 17.39 are unintelligible. Accordingly, Purdue denies the averments of Paragraph 17.39.

17.40. Purdue admits that the article "The Treatment of Cancer Pain" (NEW ENGLAND JOURNAL OF MEDICINE 1985; 313:84-95) was authored by Kathleen M. Foley,

M.D., and was published in 1985. Table 6 on page 90 of the article lists oral (PO) doses under the heading "Equianalgesic Doses" for a number of different narcotic analgesics for severe pain. The entry for morphine in Table 6 lists a 60 mg PO dose. The entry for oxycodone in Table 6 lists a 30 mg PO dose. Except as expressly admitted, Purdue denies the averments of Paragraph 17.40.

17.41. The Foley article is prior art to the '331, '912, '042, and '295 patents under one or more subsections of 35 U.S.C. § 102. Except as expressly admitted, Purdue denies the averments of Paragraph 17.41.

17.42. At least Dr. Kaiko was aware of the existence of the Foley article at least at the time he cited it in an article published in 1990. Except as expressly admitted, Purdue denies the averments of Paragraph 17.42.

17.43. Dr. Kaiko was aware of the existence of the Foley article at least at the time he cited it in an article published in 1990. Except as expressly admitted, Purdue denies the averments of Paragraph 17.43.

17.44. Table 6 on page 90 of the Foley article lists oral (PO) doses under the heading "Equianalgesic Doses" for a number of different narcotic analgesics for severe pain. The entry for morphine in Table 6 lists a 60 mg PO dose. The entry for oxycodone in Table 6 lists a 30 mg PO dose. Except as expressly admitted, Purdue denies the averments of Paragraph 17.44.

17.45. Paragraph 78 accurately quotes the cited portion of Dr. Kaiko's July 16, 1990 memo. Purdue denies Apotex's characterization of the quoted language. Except as expressly admitted, Purdue denies the averments of Paragraph 17.45.

17.46. Denied.

17.47. 10-80 mg and 5-40 mg are both eight-fold ranges. Except as expressly admitted, Purdue denies the averments of Paragraph 17.47.

17.48. A 5 mg immediate-release tablet of oxycodone was commercially available at the time of the prosecution of the '331, '912, '042, and '295 patents. Except as expressly admitted, Purdue denies the averments of Paragraph 17.48.

17.49. Denied.

17.50. Denied.

17.51. The response filed October 22, 1992 during the '331 prosecution stated that "the presently claimed controlled release oxycodone formulations acceptably control pain over a substantially narrower, approximately four-fold (10 to 40 mg every 12 hours – around the clock dosing) in approximately 90% of patients" and that "[t]his is in sharp contrast to the approximately eight-fold range required for approximately 90% of patients for opioid analgesics in general." Similar language appears on one other occasion in the '331 file history (*see* Paper #8, March 12, 1993), one occasion in the '912 file history (*see* Paper #8, February 22, 1995) and in the specification of the '912, '042, and '295 patents. Except as expressly admitted, Purdue denies the averments of Paragraph 17.51.

17.52. Denied.

17.53. Denied

17.54. Dr. Kaiko believed that his discovery, which he has at times also referred to as an insight, was a scientifically sound inference to draw from, *inter alia*, the extensive clinical work that had been done to establish that the experimental OxyContin® formulation would provide adequate pain relief without unacceptable side effects. Except as expressly admitted, Purdue denies the averments of Paragraph 17.54.

17.55. Dr. Kaiko is not an inventor of the '331 patent. Except as expressly admitted, Purdue denies the averments of Paragraph 17.55.

17.56. Denied.

17.57. Purdue has sponsored and supported numerous clinical studies, including the ones referenced by Apotex in Paragraphs 57-64. Purdue denies Apotex's characterization of these studies. Purdue did not disclose these studies to the PTO, nor was there any reason that Purdue should have disclosed them. The studies were less pertinent than and cumulative to other facts that were before the PTO. Except as expressly admitted, Purdue denies the averments of Paragraph 17.57.

17.58. The underlying work for the Kalso study ("Protocol No. OC93-0303") took place between February 22, 1994 and May 16, 1995. The underlying work for the Berman study ("Protocol No. OC92-1001") took place between June 1, 1994 and December 27, 1995. The '912 patent was filed on November 25, 1992 as a PCT application and issued on August 27, 1996. The '042 patent was filed on June 6, 1995 and issued on April 16, 1996. The '295 patent was filed on March 19, 1996 and issued on August 12, 1997. Except as expressly admitted, Purdue denies the averments of Paragraph 17.58.

17.59. Both the Kalso and Berman studies were later published in journals relevant to the field of pharmaceutical science. The article reporting the results of the Berman study included several Purdue personnel as co-authors. Except as expressly admitted, Purdue denies the averments of Paragraph 17.59.

17.60. Purdue updated the FDA with the results of the Kalso and Berman studies after the FDA had approved the OxyContin® NDA. Except as expressly admitted, Purdue denies the averments of Paragraph 17.60.

17.61. Purdue did not disclose the Kalso and Berman studies to the PTO, nor was there any reason that Purdue should have disclosed them. The studies were less pertinent than and cumulative to other facts that were before the PTO. Except as expressly admitted, Purdue denies the averments of Paragraph 17.61.

17.62. Paragraphs 17.57 and 17.62 reference the Kalso and Berman studies. Purdue denies Apotex's characterization of these studies. Dr. Kaiko signed the Kalso Study Report and co-authored the article publishing the results of the Berman study. Paragraph 17.62 accurately quotes the cited portion of the Berman article. Purdue denies Apotex's characterization of the quoted language. Except as expressly admitted, Purdue denies the averments of Paragraph 17.62.

17.63. Paragraph 17.63 accurately quotes the cited portion of Dr. Kaiko's August 22, 1996 email. Purdue denies Apotex's characterization of the quoted language. Except as expressly admitted, Purdue denies the averments of Paragraph 17.63.

17.64. Dr. Kaiko was aware of the Kalso study as of August 16, 1996**.** Except as expressly admitted, Purdue denies the averments of Paragraph 17.64.

17.65. Denied.

17.66. Purdue admits that the article "Comparative Clinical Efficacy and Safety of a Novel Controlled-Release Oxycodone Formulation and Controlled-Release Hydromorphone in the Treatment of Cancer Pain" (CANCER 1997; 79:1428-37) was co-authored by an employee of Purdue Frederick Canada. Purdue admits that the Heiskanen and Kalso article "Controlled-Release Oxycodone and Morphine in Cancer Related Pain" (PAIN 1997; 73:37-45) reported findings from a study supported by Purdue Frederick. The article states that "[d]uring the stable phases, significantly more ($P<0.05$) daily doses of escape analgesics were required during treatment with oxycodone . . . compared with morphine." Purdue admits that the Citron

article ”Long-Term Administration of Controlled Release Oxycodone Tablets for the Treatment of Cancer Pain” (CANCER INVESTIGATION, 1998; 16(8): 562-71) was co-authored by Dr. Kaiko and was based on a study sponsored by Purdue Pharma L.P. Except as expressly admitted, Purdue denies the averments of Paragraph 17.66.

17.67. Denied.

17.68. The ‘331 patent disclosed and claimed oxycodone hydrochloride as the active ingredient instead of the hydromorphone claimed and disclosed in the ‘341 and ‘909 patents. Except as expressly admitted, Purdue denies the averments of Paragraph 17.68.

17.69. Purdue disclosed the ‘341 patent to the PTO. Except as expressly admitted, Purdue denies the averments of Paragraph 17.69.

17.70. Admitted.

17.71. Admitted.

17.72. The response filed October 22, 1992 during the ‘331 prosecution stated that “the presently claimed controlled release oxycodone formulations acceptably control pain over a substantially narrower, approximately four-fold (10 to 40 mg every 12 hours – around the clock dosing) in approximately 90% of patients” and that “[t]his is in sharp contrast to the approximately eight-fold range required for approximately 90% of patients for opioid analgesics in general.” Except as expressly admitted, Purdue denies the averments of Paragraph 17.72.

17.73. Paragraph 17.73 accurately quotes the cited portion of the prosecution history of the ‘331 patent. Purdue denies Apotex’s characterization of the quoted language. Except as expressly admitted, Purdue denies the averments of Paragraph 17.73.

17.74. In an office action dated February 3, 1993, the Examiner maintained the obviousness rejection over the ‘341 patent in view of the ‘598 patent with respect to pending claims 14-17. Except as expressly admitted, Purdue denies the averments of Paragraph 17.74.

17.75. Following an interview with the Examiner, the applicants submitted at the Examiner's invitation an amendment on or about March 10, 1993. Submitted in support of the amendment was the declaration of Dr. Kaiko. Attached to that declaration was a paper that contained language similar to that quoted in Purdue's reply to Paragraph 17.72. Except as expressly admitted, Purdue denies the averments of Paragraph 17.75.

17.76. The '331 patent was filed on November 27, 1991 and issued on November 30, 1993. The '912 patent originated as PCT application no. PCT/US92/10146, filed November 25, 1992 as a continuation-in-part of the '331 patent; the PCT application entered the U.S. national phase as U.S. patent application no. 81,302 on June 18, 1993; and the U.S. patent application issued on August 27, 1996. Except as expressly admitted, Purdue denies the averments of Paragraph 17.76.

17.77. The Primary Examiner listed on the face of the '331 patent is Thurman K. Page. The Assistant Examiner listed on the face of the '331 patent is James M. Spear, who is also the "Authorized Officer" listed on the international prior art search report for PCT application no. PCT/US92/10146, from which the '912 patent originated. The Primary Examiner listed on the face of the '912 patent is Edward J. Webman. Except as expressly admitted, Purdue denies the averments of Paragraph 17.77.

17.78. The Examiner imposed a restriction requirement on the '912 claims as filed. After the restriction requirement, Purdue elected to pursue the composition claims in the '912 prosecution. Except as expressly admitted, Purdue denies the averments of Paragraph 17.78.

17.79. Admitted.

17.80. Admitted.

17.81. Admitted.

17.82. Paragraph 17.82 accurately quotes the cited portion of the prosecution history of the '912 patent except that there is no hyphen between the words "commercially available," there is a hyphen between the words "controlled-release," and the words "to control 90% of patients with significant pain" do not appear at the end of the quotation. Purdue denies Apotex's characterization of the quoted language. Except as expressly admitted, Purdue denies the averments of Paragraph 17.82.

17.83. In an amendment dated September 12, 1995, Purdue amended the specification to obtain the benefit of the filing date of the prior application pursuant to 35 U.S.C. § 120. Except as expressly admitted, Purdue denies the averments of Paragraph 17.83.

17.84. At the Examiner's suggestion, Purdue amended the specification "to obtain the benefit of the filing date of the prior application." ('912 file history, Paper #10, Sept. 12, 1995, p. 1). Purdue did not assert that any of the pending claims was entitled to the priority date of the '331 application. At no time did the Examiner or Purdue rely on the '331 filing date in response to a prior art rejection. In addition, all of the pertinent facts regarding the '331 patent were before the Examiner: the application, its disclosure, its inventors, and its dates. And the Examiner was aware that the '912 application "adds and claims additional disclosure not presented in the prior application." ('912 file history, Paper #9, June 12, 1995, p. 2). Except as expressly admitted, Purdue denies the averments of Paragraph 17.84.

17.85. The '042 patent was filed on June 6, 1995 and issued on April 16, 1996. The Primary Examiner listed on the face of the '042 patent is Edward J. Webman, who is also the Primary Examiner listed on the face of the '912 patent. Except as expressly admitted, Purdue denies the averments of Paragraph 17.85.

17.86. Paragraph 17.86 accurately quotes the cited portion of claims 1 and 2 of '912 patent. Purdue denies Apotex's characterization of the quoted language. Except as expressly admitted, Purdue denies the averments of Paragraph 17.86.

17.87. Denied.

17.88. In the first office action during the '042 prosecution, the Examiner cited no art but issued an objection under the first paragraph of 35 U.S.C. § 112 and rejections under both the first and second paragraphs of 35 U.S.C. § 112. Except as expressly admitted, Purdue denies the averments of Paragraph 17.88.

17.89. After the first office action during the '042 prosecution, an interview with the Examiner was held. The Examiner Interview Summary Record ('042 file history, Paper #5, December 26, 1995) states that "to bring the case into condition for allowance, it [was] agreed to delete 'substantially' in claims 1, 2." The claims were then allowed. ('042 file history, Paper #6, December 26, 1995). Paragraph 17.89 accurately quotes the cited portion of the prosecution history of the '042 patent except that the last word in the quote should be "dosages," not "doses." Except as expressly admitted, Purdue denies the averments of Paragraph 17.89.

17.90. Purdue denies Apotex's characterization of the clinical studies referenced in Paragraph 17.90. Purdue did not disclose these studies to the PTO, nor was there any reason that Purdue should have disclosed them. The studies were less pertinent than and cumulative to other facts that were before the PTO. Paragraph 17.90 accurately quotes the cited portion of '042 claim 1. Purdue denies Apotex's characterization of the quoted language. Except as expressly admitted, Purdue denies the averments of Paragraph 17.90.

17.91. Denied.

17.92. Denied.

17.93. Denied.

17.94. The specification of the '331 patent includes the following statement: "The present inventors have surprisingly found that, in the case of oxycodone, a peak plasma level at between 2-4 hours after administration gives at least 12 hours pain relief, and most surprisingly, that the pain relief obtained with such a formulation is greater than that achieved with formulations giving peak plasma levels (of oxycodone) in the normal period of 1-2 hours after administration." ('331 patent, col. 2, lines 21-28). Paragraph 17 of the declaration by Dr. Kaiko submitted with the March 10, 1993 Amendment during the '331 prosecution states "[o]ne skilled in the art would not be able to accurately predict whether an oxycodone formulation with the in vitro dissolution taught in the Oshlack '598 patent would provide the pharmacokinetics (including the tmax) . . . set forth in the claims of the presently considered patent application." ('331 file history, Paper #8, March 10, 1993, pp. 5-6). Except as expressly admitted, Purdue denies the averments of Paragraph 17.94.

17.95. Paragraph 17.95 accurately quotes portions of the March 10, 1993 Amendment submitted during the '331 prosecution. Purdue denies Apotex's characterization of the quoted language. Except as expressly admitted, Purdue denies the averments of Paragraph 17.95.

17.96. A declaration by Dr. Kaiko was submitted with the March 10, 1993 Amendment during the '331 prosecution. Except as expressly admitted, Purdue denies the averments of Paragraph 17.96.

17.97. Dr. Kaiko identified himself as Vice President for Clinical Research for The Purdue Frederick Company, Norwalk, Connecticut. Paragraph 17.97 accurately quotes the cited portions of the prosecution history of the '331 patent. Except as expressly admitted, Purdue denies the averments of Paragraph 17.97.

17.98. The ‘331 specification did not disclose Euroceltique’s relationship to Purdue and did not disclose that Dr. Kaiko was a co-inventor on the co-pending PCT application that was filed as continuation-in-part of the ‘331 application and that later issued as the ‘912 patent. Except as expressly admitted, Purdue denies the averments of Paragraph 17.98.

17.99. Purdue denies that its argument was directly contrary to the teaching of the prior art ‘598 patent also assigned to Euroceltique, and accordingly denies every other averment of Paragraph 17.99.

17.100. Mr. Oshlack was named as an inventor on the ‘598, ‘331, ‘912, ‘042, and ‘295 patents. Except as expressly admitted, Purdue denies the averments of Paragraph 17.100.

17.101. Denied.

17.102. The prosecution histories of the ‘331, ‘912, ‘042, and ‘295 patents do not indicate that Purdue and its attorneys cited the ‘984 patent to the PTO during the prosecution of the ‘331, ‘912, ‘042, and ‘295 patents. The ‘984 patent is cumulative to and less pertinent than art that was cited. Except as expressly admitted, Purdue denies the averments of Paragraph 17.102.

17.103. Paragraph 17.103 correctly states the application serial number, filing date, and issue date for the ‘984 patent. It also correctly states the named inventors of the ‘984 patent except that Sandra Malkowska’s middle initials are T.A., not T.Z. The inventors listed on the face of the ‘984 patent are the same as those listed on the face of the ‘341 patent. Except as expressly admitted, Purdue denies the averments of Paragraph 17.103.

17.104. The ‘341 patent is prior art to the ‘331, ‘912, ‘042, and ‘295 patents under one or more subsections of 35 U.S.C. § 102. Except as expressly admitted, Purdue denies the averments of Paragraph 17.104.

17.105. The *in vitro* dissolution rate ranges of claim 1 of the '984 patent overlap with the *in vitro* dissolution rate ranges of claim 1 of the '331 patent, claim 7 of the '912 patent, and claim 1 of the '341 patent. Except as expressly admitted, Purdue denies the averments of Paragraph 17.105.

17.106. The controlled-release dihydrocodeine formulations disclosed in Examples 1-6 of the '984 patent are described as providing peak plasma levels at between 2-4 hours and 12 hours of pain relief. Except as expressly admitted, Purdue denies the averments of Paragraph 17.106.

17.107. The specification of the '331 patent includes the following statement: "The present inventors have surprisingly found that, in the case of oxycodone, a peak plasma level at between 2-4 hours after administration gives at least 12 hours pain relief, and most surprisingly, that the pain relief obtained with such a formulation is greater than that achieved with formulations giving peak plasma levels (of oxycodone) in the normal period of 1-2 hours after administration." ('331 patent, col. 2, lines 21-28). The specifications of the '912, '042, and '295 patents include similar language. (*See, e.g.*, '912 patent, col. 5, lines 9-16). Except as expressly admitted, Purdue denies the averments of Paragraph 17.107.

17.108. Paragraph 17.108 accurately quotes portions of the '984, '341, and '331 patents. Purdue denies Apotex's characterization of the quoted language. The '984 and '341 patents are prior art to the '042 patent under one or more subsections of 35 U.S.C. § 102. Except as expressly admitted, Purdue denies the averments of Paragraph 17.108.

17.109. The '984 patent issued on May 30, 1989. The '341 patent issued on February 5, 1991. PCT application no. PCT/US92/10146 was filed on November 25, 1992. Except as expressly admitted, Purdue denies the averments of Paragraph 17.109.

17.110. The ‘331 patent was filed on November 27, 1991 and issued on November 30, 1993. The ‘912 patent originated as PCT application no. PCT/US92/10146, filed November 25, 1992 as a continuation-in-part of the ‘331 patent; the PCT application entered the U.S. national phase as U.S. patent application no. 81,302 on June 18, 1993; and the U.S. patent application issued on August 27, 1996. Except as expressly admitted, Purdue denies the averments of Paragraph 17.110.

17.111. Denied.

17.112. Denied.

17.113. The ‘912 specification discloses:

> Repeated dose studies with the controlled release oxycodone formulations administered every 12 hours in comparison with immediate release oral oxycodone administered every 6 hours at the same total daily dose result in comparable extent of absorption, as well as comparable maximum and minimum concentrations. The time of maximum concentration occurs at approximately 2-4.5 hours after oral administration with the controlled-release product as compared to approximately 1 hour with the immediate release product. Similar repeated dose studies with MS Contin® tablets as compared to immediate release morphine provide for comparable relative results as with the controlled release oxycodone formulations of the present invention.

Purdue also disclosed the ‘341 patent to the PTO. Except as expressly admitted, Purdue denies the averments of Paragraph 17.113.

17.114. Denied.

17.115. Denied.

17.116. Denied to the extent that the “prior formulations” of Paragraph 17.116 reference the “four other prior art opioid analgesic drugs” of Paragraph 17.115 and further denied to the extent that the ‘984 patent does not disclose MS Contin®.

17.117. Denied to the extent that Paragraph 114 does not refer to four prior formulation patents.

17.118. Denied.

17.119. The Primary Examiner listed on the face of the ‘428 patent is Shep K. Rose. The Primary Examiner listed on the face of the ‘984, ‘341, and ‘331 patents is Thurman K. Page. The Assistant Examiner listed on the face of the ‘331 patent is James M. Spear. The Primary Examiner listed on the face of the ‘912, ‘042, and ‘295 patents is Edward J. Webman. Except as expressly admitted, Purdue denies the averments of Paragraph 17.119.

17.120. During the ‘331 prosecution, Purdue submitted a terminal disclaimer giving up the portion of the term of the ‘331 patent beyond the expiration date of the ‘341 patent. Except as expressly admitted, Purdue denies the averments of Paragraph 17.120.

17.121. Admitted.

17.122. Admitted.

17.123. Admitted.

17.124. Denied.

17.125. The ‘042 patent has not yet expired. Except as expressly admitted, Purdue denies the averments of Paragraph 17.125.

17.126. Denied.

17.127. Denied.

17.128. Denied.

17.129. Denied.

17.130. Purdue submitted the ‘042 patent to the FDA to be listed in the Orange Book. Except as expressly admitted, Purdue denies the averments of Paragraph 17.130.

18. Purdue repeats and incorporates its reply to Paragraphs 1-17.

19. Denied.

REPLY TO COUNTERCLAIM COUNT II

20. Purdue repeats and incorporates its reply to Paragraph 17, including subparagraphs 17.20-130.

21. Purdue repeats and incorporates its reply to Paragraphs 1-20.

22. Paragraph 22 correctly identifies the filing date and issue date of the ‘331 patent but incorrectly states its application serial number; the correct serial number is 07/800,549. The ‘912 patent was filed as a continuation-in-part of the ‘331 patent application as PCT application no. PCT/US92/10146 filed November 25, 1992 and entered the U.S. national phase as U.S. patent application no. 81,302 on June 18, 1993. Paragraph 22 correctly identifies the issue date, application number, filing date, and divisional status of the ‘042 patent. Except as expressly admitted, Purdue denies the averments of Paragraph 22.

23. Denied.

REPLY TO COUNTERCLAIM COUNT III

24. Purdue repeats and incorporates its reply to Paragraph 17, including subparagraphs 17.20-130.

25. Purdue repeats and incorporates its reply to Paragraphs 1-24.

26. Denied.

27. Denied.

REPLY TO COUNTERCLAIM COUNT IV

28. Purdue repeats and incorporates its reply to Paragraph 17, including subparagraphs 17.20-130.

29. Purdue repeats and incorporates its reply to Paragraphs 1-24.

30. Denied.

31. Denied.

32. Purdue repeats and incorporates its reply to Paragraph 17, including subparagraphs 17.23-126. Except as expressly admitted, Purdue denies the averments of Paragraph 32.

33. Denied.

34. Denied.

REPLY TO COUNTERCLAIM COUNT V

35. Purdue repeats and incorporates its reply to Paragraph 17, including subparagraphs 17.20-130.

36. Purdue repeats and incorporates its reply to Paragraphs 1-35.

37. The entry of generic drugs into a market may or may not increase competition depending on economic and other market factors. Except as expressly admitted, Purdue denies the averments of Paragraph 37.

38. The number of generic competitors in a market may or may not affect drug prices, depending on economic and other market factors. Except as expressly admitted, Purdue denies the averments of Paragraph 38.

39. Denied.

40. Denied.

41. Denied.

42. Denied.

43. Denied.

44. Denied.

45. Denied.

46. Denied.

47. Denied.

48. Denied.

49. Denied.

50. Purdue lacks information sufficient to form a belief about the averments of Paragraph 50, and therefore denies them.

51. Purdue lacks information sufficient to form a belief about the averments of Paragraph 51, and therefore denies them.

52. Denied.

53. Purdue denies that it has engaged in an anticompetitive scheme. Paragraph 53 otherwise states a conclusion of law to which no responsive pleading is necessary. Except as expressly admitted, Purdue denies the averments of Paragraph 53.

54. Purdue denies that it has engaged in exclusionary conduct. Purdue lacks information sufficient to form a belief about the remaining averments of Paragraph 54, and therefore denies them.

55. Denied.

56. Denied.

57. Denied.

58. Denied.

DEFENSES

59. Purdue's '042 patent is not invalid and is enforceable.

60. Apotex has infringed and will infringe under 35 U.S.C. § 271 the claims of the '042 patent.

61. Purdue has not violated Section One of the Sherman Act (15 U.S.C. § 1).

62. Purdue has not violated Section Two of the Sherman Act (15 U.S.C. § 2).

63. Purdue has not violated any state antitrust law.

WHEREFORE, Purdue prays for judgment:

A. Dismissing Apotex's Counterclaims;

B. Adjudging that the '042 patent is valid and enforceable;

C. Adjudging that Apotex has infringed the '042 patent and that such infringement has been willful and deliberate;

D. Adjudging, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Apotex's ANDA No. 78-840 under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) to be a date which is not earlier than the date of expiration of the '042 patent;

E. Preliminary and permanently enjoining, pursuant to 35 U.S.C. §§ 271(e)(4)(B) and 283 and Rule 65, Fed. R. Civ. P., defendant Apotex, its officers, agents, servants, employees, parents, subsidiaries, affiliate corporations, other related business entities and all other persons acting in concert, participation or in privity with them, and their successors and assigns, from any commercial manufacture, use, offer to sell or sale within the United States, or importation into the United States, of any drug product that infringes the '042 patent;

F. Awarding Purdue damages, together with prejudgment interest and costs, as provided by 35 U.S.C. §§ 271(e)(4)(C) and 284;

G. Trebling the damages awarded, as provided by 35 U.S.C. § 284;

H. Declaring this an exceptional case and awarding Purdue its attorney's fees, as provided by 35 U.S.C. §§ 271(e)(4) and 285; and

I. Awarding Purdue such other and further relief as this Court may deem just and proper.

ROPES & GRAY LLP

November 26, 2007

s/Richard A. Inz

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CERTIFICATE OF SERVICE

I hereby certify that on November 26, 2007, I caused to be electronically filed PURDUE'S REPLY TO THE COUNTERCLAIMS SET FORTH IN DEFENDANTS APOTEX, INC.'S AND APOTEX CORP.'S ANSWERS, DEFENSES AND COUNTERCLAIMS with the Clerk of the Court via CM/ECF. Notice of this filing will be sent by e-mail to all parties by operation of the court's electronic filing system. Parties may access this filing through the court's CM/ECF System.

s/Richard A. Inz
Richard A. Inz